

# CHANGES TO SUBMISSION REQUIREMENTS READ CAREFULLY

## FISCAL YEAR 2012 NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES CANCER AND SMOKING DISEASE RESEARCH FUNDS GRANT APPLICATION GENERAL INSTRUCTIONS

Applications for Fiscal Year 2012 Cancer and Smoking Disease Research Grant funding will be accepted by the Nebraska Department of Health and Human Services between December 1, 2010 and February 7, 2011. As of December 1, 2010, application formats and instructions will be available through the Nebraska Department of Health and Human Services website or by contacting Mary Weatherfield at (402)471-0925 or E-mail:mary.weatherfield@nebraska.gov.

**Applications must be received by 5:00 p.m. on Monday, February 7, 2011 in order to be considered for funding in Fiscal Year 2012. There will be no exceptions to this deadline.**

Applications will receive initial screening by the Department staff. During this review process, a determination will be made as to each application's consistency with the intent of the legislation. Only applications, which propose research relating to cancer and/or smoking diseases, will be considered for funding. **A clear statement of the project's relevancy to cancer or smoking disease must be included in the abstract.** Those applications not meeting the intent of the legislation will be excluded from further consideration and will be returned without review.

Those applications found to be consistent with the legislative intent will be referred to the FY **2012** Nebraska Cancer and Smoking Disease Research Technical or Behavioral Review Committees. These committees will be composed of scientists and physicians who have no affiliation with Nebraska universities. Names of the members of these Committees will be provided by the Department when the review is completed. The review will be based upon the following criteria specified in Neb. Rev. Stat. 81-639 (Reissue 1994) which are:

- 1) The relevancy of the applicant's proposal to the furthering of cancer research and smoking disease research;
- 2) The feasibility of the applicant's proposal;
- 3) The availability of other sources of funding for the applicant's proposal;
- 4) The facilities, personnel, and expertise available to the applicant for use in the proposal; and
- 5) Evidence of the quality of the applicant's prior or existing programs for research of cancer and smoking diseases or the applicant's potential for developing new programs for such research.

Reviewers will also be asked to critique the application's innovativeness, strengths and weaknesses, as well as to make suggestions for budget modifications. It will be the responsibility of the Review Committees to assess the scientific merit of each proposal and develop a recommendation to the Department of Health and Human Services regarding the rank order of all

applications under consideration. This ranking will be used to determine which proposals will receive funding.

Based on the Review Committees rankings and the statutory criteria, the Department of Health and Human Services staff will make recommendations to the Director regarding those proposals to be funded. The Director has the final decision-making authority for determining which applications will be funded. The Department will notify applicants by the end of May 2011 as to which proposals will be funded in FY **2012**. Funding begins on July 1, 2011 for those proposals selected for funding. All decisions are contingent upon continued funding of this program by the Nebraska Legislature.

### **ONLY APPLICATIONS FOR ONE YEAR PROJECTS WILL BE CONSIDERED**

The Department will consider applications proposing one-year projects only with a budget of up to \$40,000. Approved applications will be funded for one year. One year projects are not eligible for renewal.

### **REVISED APPLICATIONS (Those submitted previously, but not funded)**

In an introduction not to exceed one (1) page, summarize any substantial additions, deletions, and changes that have been made. Include responses to criticisms in the previous summary statement. Highlight these changes within the text of the Research Plan by appropriate bracketing, indenting, or changing of typography. Incorporate in the Progress Report/Preliminary Studies Section any work done since the prior version was submitted. A revised application will not be funded if substantial revisions are not clearly apparent.

### **CHANGES IN PRINCIPAL INVESTIGATORS WILL BE REVIEWED ON A CASE BY CASE BASIS**

Because one of the criteria for reviewing research applications is the qualifications of the principal investigator, a change in principal investigators after an application has been reviewed and approved for funding will not be approved without a thorough review of the qualifications of the new principal investigator.

### **APPROVALS FOR USE OF HUMAN SUBJECTS, ANIMALS, AND RECOMBINANT DNA**

Each application to the Department of Health and Human Services requires that the following certifications be provided, as appropriate:

Human Subjects  
Vertebrate Animals  
Recombinant DNA

The certifications listed above are made by checking the appropriate boxes on the **FACE PAGE**. They are verified by signature of the **Official Signing for Applicant Organization** on the **FACE PAGE** of the application.

Nebraska Cancer and Smoking Disease Research Program  
Timeline for FY **2012**

Public Announcement of Review Cycle.....	December 1, 2010
Application Information Available to Researcher.....	December 1, 2010
Deadline for Receipt of Proposals.....	February 7, 2011
Department Screening Completed.....	Week of March 14, 2011
Certifications for Human Subjects, Animals, and Recombinant DNA Must be Received by Departments.....	April 4, 2011
Review Panel Convenes.....	TBA
Announcement of Grant Awards.....	May 31, 2011
Contracts with Universities Completed.....	June 30, 2011
Funding Begins.....	July 1, 2011
Six Month Progress Reports Due.....	January 31, 2012
Funding Period Ends.....	June 30, 2012
Final Progress Reports Due.....	September 30, 2012
Final Financial Reports Due.....	September 30, 2012

FISCAL YEAR 2012  
NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CANCER AND SMOKING DISEASE RESEARCH FUNDS

**SPECIFIC INSTRUCTIONS - SECTION 1.**

**\*\*\* READ AND FOLLOW THE INSTRUCTIONS CAREFULLY TO AVOID DELAYS  
AND MISUNDERSTANDINGS \*\*\***

**SUBMISSION**

**TO BE CONSIDERED FOR FUNDING, BIOMEDICAL/BASIC SCIENCE PROPOSALS  
AND/OR BEHAVIORAL SCIENCE PROPOSAL, APPLICATES:**

- (1) USE THE APPLICATION PROVIDED ON THE NEBRASKA (DHHS) CANCER AND  
SMOKING DISEASE RESEARCH FUNDS WEB SITE;AND**
- (2) EMAIL THE COMPLETED APPLICATION AS A PDF DOCUMENT.\***
- (3) TITLE THE PDF DOCUMENT USING THE FORMAT: PRINCIPAL  
INVESTIGATOR/PROGRAM DIRECTOR (LAST, FIRST, MIDDLE) LB506 2012**
- (4) THE PDF DOCUMENT MUST CONTAIN THE SCANNED PAGES OF THOSE  
PAGES WITH REQUIRED SIGNATURES AND ANY LETTERS.**

**\*See Section 3 for instructions on e-mailing the Appendix.**

Applicants may not substitute application form pages from **other sources** for Nebraska  
Department of Health and Human Services form pages in the application kit. **See Section 3 for  
instructions on Appendix.**

All pages must be on paper that is 8 ½" x 11" and typed on one side only. Standard one inch margins for top, side and bottom margins. Page limitations apply to sections of the application. A prohibition has been placed on the use of type fonts that are smaller than computer 12-point and on the use of photoreduction. Using 12-point, characters per inch will vary depending on font type selected; 12 - 16 characters per inch are acceptable.

Figures, charts, tables, and footnotes may be smaller size but must be clear and readily legible. In addition, dot matrix printing should not be used. The applications will be returned without review if the page limitations are exceeded, if type fonts are used that are too small, or if photoreduction is used on any of the pages.

Do not submit an incomplete application. **Principal investigators** should review their applications before submitting for missing, misnumbered, or out-of-order pages, incorrect data on tables and graphs, and errors in the budgets. The Department of Health and Human Services does not guarantee that corrected or missing information will be forwarded to reviewers. The only material accepted for forwarding is updated information in preliminary research that may enhance the review of the application. **An application will be considered incomplete and returned if it fails to follow the instructions or if the material presented is insufficient to permit an adequate review.**

Applications must be received by 5:00 p.m. on Monday, February 7, 2011. Email a pdf document of the completed application, including the required signature pages, to: [mary.weatherfield@nebraska.gov](mailto:mary.weatherfield@nebraska.gov).

## **FACE PAGE**

**Item 1. Title of Project.** Choose a title that is descriptive and specifically appropriate, rather than general. Do not exceed 56 typewriter spaces, including the spaces between words and punctuation. A **NEW** application must have a different title from any other project funded by the Nebraska Cancer and Smoking Disease Research Program with the same principal investigator. A **REVISED** application would ordinarily have the same title. If the specific aims of the revised application have changed significantly, choose a new title.

**Item 2. Name of Principal Investigator.** Name the one person responsible to the applicant organization for the specific and technical direction of the project.

**Item 2a. Degree(s).** Indicate academic and professional degrees. Include initial professional education.

**Item 2b. Position Title.** If the principal investigator has more than one title, indicate the one most relevant to the proposed project, such as Professor of Biochemistry, Chief of Surgical Service, or Group Leader.

**Item 2c. Mailing Address.** Self-explanatory.

**Item 2d. Department, Service, Laboratory, or Equivalent.** Indicate the organizational affiliation.

**Item 2e. Major Subdivision.** Indicate the school, college, or other major subdivision, such as medical, dental, engineering, graduate, nursing, or public health. If there is no such subdivision, enter "none."

**Item 2f. Telephone and FAX Numbers.** Self-explanatory.

**Item 2g. New Application; Revised Application.** Check appropriate box. If the application replaces a prior unfunded version of a new competing application, insert the number of the previous application.

**Item 3. Human Subjects.** If activities involving human subjects are not planned **at any time** during the proposed project period, check the box marked "NO." If activities involving human subjects, whether or not exempt from Institutional Review Board regulations for the protection of human subjects, are planned **at any time** during the proposed project period, check the box marked "YES."

Insert the date of approval by the applicant organization's review board for the protection of human subjects. If the activities are designated to be exempt from the regulations, insert the date the exemption was approved by the applicant organization's review board for protection of human subjects.

**Item 4. Vertebrate Animals.** If activities involving vertebrate animals are not planned **at any time** during the proposed project period, check the box marked "NO." If activities involving vertebrate animals are planned **at any time** during the proposed project period, check the box marked "YES." Insert the date of approval by the applicant organization's review board for the humane treatment and use of vertebrate animals.

**Item 5. Recombinant DNA.** If activities involving recombinant DNA are not planned **at any time** during the proposed project period, check the box marked "NO." If activities involving recombinant DNA are planned **at any time** during the proposed project period, check the box marked "YES." Insert the date of approval by the applicant organization's review board for biosafety.

**\*\* NOTE \*\***

To ensure against delays in the review of the application, certifications are best completed prior to submission of the application. If certifications are unavoidably delayed beyond the submission of the application, enter "**pending**" at Item 3, 4, and/or 5. A follow-up certification of approval must then be sent to and received by the Nebraska Department of Health and Human Services within 45 days after the receipt date for which the application is submitted. This follow-up certification must include: application number, title of the application project, name of the principal investigator and institution, and date of the certification review approval or exemption.

Any modifications in the Research Plan section of the application required by review boards for human subjects, vertebrate animals, or recombinant DNA must be submitted with the follow-up certification.

**It is the responsibility of the Principal Investigator to submit the follow-up certification. The Department of Health and Human Services does not guarantee that it will remind the principal investigator/program director to provide this missing information. If certification of approvals for human subjects, vertebrate animals, and/or recombinant DNA is not received when due, i.e., within 45 days after the official application receipt date, the application will be considered incomplete and will be returned without review.**

**Item 6. Total Direct Costs for Entire Proposed Project Period.** Enter the total direct costs from the budget, Form Page 4.

**Item 7. Name of Administrative Official To Be Notified If An Award Is Made.** Self-explanatory.

**Item 8. Name of Official Signing For Applicant Organization.** Name an individual authorized to act for the applicant organization and to assume the obligations imposed by the requirements and conditions for any grant.

**Item 9. Principal Investigator Assurance.** Self-explanatory.

**Item 10. Applicant Organization Certification and Acceptance.** Self-explanatory.

## **FORM PAGE 1**

**Table of Contents.** Self-explanatory.

## **FORM PAGE 2**

**Description.** Self-explanatory.

**Key Personnel.** Key personnel are defined as, and should be limited to, individuals who contribute in a substantive way to the scientific development or execution of the project, whether or not salaries are requested. ***The PI must be an independent investigator with an appropriate faculty appointment, adequately assigned laboratory space, and the ability to apply for federal grants as a PI.***

***Junior applicants may apply if they provide a statement or letter from their Chairperson specifically confirming their faculty level appointment, the amount of independent research space available to them and that they are considered eligible to apply for federal grants as a PI.***

Consultants should be included only when their level of involvement meets the definition. Individuals providing technical services are not considered key personnel. For each individual, provide: name, organization, and role on the project. Under role on the project, indicate how the individual will function with regard to the proposed project, for example, principal investigator, graduate research assistance, etc. Use additional pages as necessary.

## **FORM PAGE 3**

**Type of Expertise Needed to Review Application.** This information will be used as the basis for assigning the application to the appropriate reviewers.

## **FORM PAGE 4**

**Detailed Budget For Project Period.** List only the direct costs requested in this application. Direct costs are those that can be identified specifically within a particular cost objective. Indirect costs or overhead costs are unallowable.

The budget sheet on Form Page 4 of the application must be completed for funding proposed in Fiscal Year 2011. Only one year proposals will be considered. The budget justification (Form Page 5) should be given special attention. The budget maximum is \$40,000.

Applications which fail to present itemized budgets and justification will be judged incomplete and will not be considered for funding.

**Personnel.** Personnel costs should include salaries, wages, and associated fringe benefits paid for services rendered to the research project. Personnel costs should be budgeted in relation to the amount of time and effort expected to be devoted to the project by each individual involved. Salary support for the Principal Investigator or other faculty on full-time appointments (12 months) will not be permitted on these grants. Faculty who have 9 or 10 month appointments

may request summer salary only. Personnel costs should be itemized by position title.

Whether or not salaries are requested, list the names and roles of all applicant organization personnel to be involved in the project during the 12-month budget period. Starting with the Principal Investigator, list all key personnel first and then support personnel. (See A. Key Personnel for definition.) Support personnel are those individuals who provide administrative or technical assistance to the project, i.e., dish-washers, animal caretakers, histopathology technicians, electron microscopy technicians, and in some instances research technicians or associates.

**Column 1: Type of Appointment.** List the number of months per year reflected in an individual's contractual appointment to the applicant organization. The Department of Health and Human Services staff assume that appointments of the applicant organization are full-time for each individual. If an appointment is less than full-time (i.e., 2 time or 3/4), enter an asterisk (\*) after the number of months and provide a full explanation under Budget Justification, on Form Page 5. Individuals may have split appointments, for example, for an academic period and a summer period. For each appointment, identify and enter the number of months on separate lines. In cases where no contractual appointment exists with the applicant organization and salary is being requested, enter the number of months for that period.

**Column 2: Percent of Effort on Project.** Indicates the percent of each appointment at the applicant organization to be devoted to this project.

**Column 3: Institutional Base Salary.** Institutional base salary is defined as the annual compensation that the applicant organization pays for the individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of duties to the applicant organization. Base salary **may not** be increased as a result of replacing institutional salary funds with grant funds.

#### **Dollar Amount Requested**

**Salary Requested.** Enter the dollar amounts for each position for which funds are requested. The maximum salary that may be requested is calculated by multiplying the individual's base salary, defined above, by the percent of effort on this project.

**Fringe Benefits.** Fringe benefits may be requested in accordance with the **existing** rate established by the applicant organization.

**Totals.** Calculate the totals for each position and enter the **subtotals** in each column where indicated.

**Consultant Costs.** Whether or not costs are involved, provide the names and organizational affiliations of any consultants, including physicians in connection with patient care, who have agreed to serve in that capacity. Consultants are usually individuals organizationally separate from the Principal Investigator. Consultant fees are not allowed for full-time faculty or researchers in other departments of the same institution of the Principal Investigator. Briefly describe under



Budget Justification on Form Page 5, the services to be performed, including the number of days of consultation, the expected rate of compensation, travel, per diem, and other related costs.

**Equipment.** Although equipment costs are usually unallowable, there may be some exceptions for scientific equipment, which must be thoroughly justified under Budget Justification, Form Page 5. Each item of equipment must be identified and the cost assigned. Any equipment purchased with research funds is the property of the Nebraska Cancer and Smoking Disease Research Program and may be assigned to other researchers in subsequent years. **No office equipment will be allowed.**

**Supplies.** Supplies, both laboratory and office, that are expected to be consumed in the conduct of the project should be budgeted. Itemize supplies in separate categories such as glassware, chemicals, radioisotopes, office supplies, etc. If animals are involved, state the species, the number to be used, their unit purchase cost, their unit care cost, and the number of care days. Under Budget Justification, Form Page 5, describe why this type and number of animal is necessary.

**Travel.** Travel expenses are allowable only when incurred for the purposes of collecting, receiving, or delivering samples. State, under Budget Justification, Form Page 5, the purpose of any travel, giving the number of trips involved, the destinations, and the number of individuals for whom funds are requested. **Travel expenses to attend national, international, professional research or educational conferences are not allowed.**

**Patient Costs.** If justified, charges for blood samples, x-rays, physical examinations, or comparable procedures are allowed for human subjects involved in the research. Patient costs do **not** include travel, lodging, or subsistence. **Treatment costs are unallowable.** Treatment costs are costs which are usual and customary. Costs specifically required to conduct the research and which will not continue after the conclusion of the study are allowed. Any requests for patient costs should be thoroughly explained under Budget Justification, Form Page 5.

**Contractual or Third Party.** Contractual or third party arrangements may involve costs such as personnel, supplies, and any other allowable expenses, for the relatively independent conduct of a portion of the work described in the Research Plan. **A grant recipient shall not subcontract for all necessary services with a single entity to implement the project.** Such costs should be thoroughly described under Budget Justification, Form Page 5. **Indirect costs are not allowed.**

**Other Expenses.** Other expenses include postage, data processing, and other types of operating expenses not classified elsewhere in these instructions. These costs will only be allowable to the extent that they are incurred for the direct benefit of an approved grant (e.g., postage, copy and printing costs for forms, correspondence, and reports required or generated by an approved grant). **The cost of publishing the findings in a scientific journal will be allowed up to \$500.** Each item in this cost category must be identified with its associated costs. In general, telephone costs are not allowable except long distance calls required by the nature of the project. Indirect or overhead costs, such as rent and utilities, are not allowable.

## **FORM PAGE 5**

**Budget Justification.** Follow specific instructions for each budget category previously described above. Describe the specific functions of the personnel, collaborators, and consultants. Explain and justify purchase of major equipment, unusual supplies requests, animal costs, and travel.

## **FORM PAGE 6**

**Biographical Sketch.** This section should contain the biographical sketches of all **key personnel**, as listed on Form Page 2. **Do not exceed two pages (Form Page 6 and one additional page) for each biographical sketch.**

## **FORM PAGE 7**

**Previous Projects Funded By This Program.** List all previous grant titles funded through the Cancer and Smoking Disease Research Program, resulting funding from other external agencies (state or federal), and any resulting publications from each grant.

## **FORM PAGE 8** (Refer to sample format)

**Other Support.** Other support is defined as **all financial resources**, whether Federal, non-Federal, commercial or institutional, **available in direct support of the Principal Investigator's research endeavors**, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards.

**Explanation of Format.** Information on other support should be provided in the format shown on page 12, using continuation pages as necessary. Include the principal investigator's name at the top and number consecutively with the rest of the application. **The sample is intended to provide guidance regarding the type and extent of information requested.**

Information on active and pending other support is required for the principal investigator only. If the principal investigator has no active or pending support, indicate "None". The application under consideration should not be listed as other support.

If the support is provided under a consortium/subcontract arrangement or is part of a multi-project award, indicate the project number, principal investigator, and source for the overall project and provide all other information for the subproject only.

## FORM PAGE 8 SAMPLE FORMAT

<b>NAME OF PRINCIPAL INVESTIGATOR</b> <u>ACTIVE/PENDING</u>		
Project Number (Principal Investigator) Source Title of Project ( <i>or Subproject</i> ) The major goals of this project are.....	Dates of Approved/Proposed Project Annual Direct Costs	Percent Effort
<u>OVERLAP</u> ( <i>summarized for each active/pending project</i> )		

## SAMPLE

SMITH, J.T.

### ACTIVE

R29 CA00000 (Jackson)	1/1/07 - 12/31/09	50%
NIH/NHLBI	\$350,000	
New Irreversible Inhibitors for Amino Acid Decarboxylases		

The major goal of this project is to develop three new classes of irreversible inhibitors for amino acid decarboxylases and to establish their mechanism of inhibition.

### PENDING

AHA9500333 (Smith)	12/01/07 - 11/30/08	10%
American Heart Association	\$80,000	
Transition State Analog Inhibitors for Phosphatases		

The major goal of this project is directed at the first synthesis of hydrolytically stable, transition state analog inhibitors of phosphohydrolases.

### OVERLAP

There is complete overlap between the American Heart Association (AHA9500333) application and the application under consideration. If both are funded, the Department of Health and Human Services grant will be returned.

## Instructions for Selected Items

**Project Number:** If applicable, include a code or identifier for the project.

**Source:** Identify the agency, institute, foundation, or other organization that is providing the support.

**Major Goals:** Provide a brief statement of the overall objectives of the project, subproject, or subcontract.

**Dates of Approved/Proposed Project.** Indicate the inclusive dates of the project as approved/proposed. For example, in the case of NIH support, provide the dates of the approved/proposed competitive segment.

**Annual Direct Costs.** In the case of an active project, provide the current year's direct cost budget. For a pending project, provide the proposed direct cost budget for the initial budget period.

**Percent Effort.** For an active project, provide the level of effort (even if unsalaried) as approved for the current budget period. For a pending project, indicate the level of effort as proposed for the initial budget period. In cases where the principal investigator's appointment is divided into academic and summer segments, indicate the proportion of each devoted to the project.

**Overlap.** After listing all support, summarize any potential overlap with the active or pending projects and this application in terms of the science, budget, or an individual's committed effort. Any necessary resolution of overlap due to this application being funded will occur in conjunction with the applicant institution and awarding agency staff at the time of award.

Overlap is defined as:

**Budgetary overlap** occurs when duplicate or equivalent budgetary items (e.g. equipment, salary) are requested in an application but are already funded or provided for by another source.

**Commitment overlap** occurs when the principal investigator has time commitments exceeding 100 percent. This is the case whether or not the grant includes salary support for the effort.

**Scientific overlap** occurs when: (1) substantially the same research is proposed in more than one application or is submitted to two or more different funding sources for review and funding consideration; or (2) a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more applications or awards, regardless of the funding source.

## **FORM PAGE 9**

**Active or Pending Support Abstract.** An abstract of each source of active or pending support is an important part of the review and award process and must be included in this application.

## **FORM PAGE 10**

**Resources and Environment.** Complete this section carefully. The information provided is important to the review process.

## SPECIFIC INSTRUCTIONS - SECTION 2.

**Research Plan.** Include sufficient information in Section 2 to facilitate an effective review without reference to any previous application. Be specific and informative and avoid redundancies. Reviewers often consider brevity and clarity in the presentation to be indicative of a principal investigator's focused approach to a research objective and ability to achieve the specific aims of the project.

Section A is specific to revised applications only. All revised applications must include an introduction. **Do not exceed one page for the introduction.** Summarize any substantial additions, deletions, and changes that have been made. **The introduction must include responses to criticisms in the previous summary statement.** Highlight these changes within the text of the Research Plan by appropriate bracketing, indenting, or changing of typography. Do not underline or shade changes. Incorporate in the section on Preliminary Studies any work done since the prior version was submitted. **A revised application will be returned if it does not address criticisms in the previous summary statement and/or an introduction is not included and/or substantial revisions are not clearly apparent.**

Organize Sections B-E of the Research Plan to answer these questions. (A) What do you intend to do? (B) Why is the work important? (C) What has already been done? (D) How are you going to do the work? Do not exceed 12 pages for Sections B-E. All tables and graphs must be included within the 12-page limit of Sections B-E. Full-sized glossy photographs of material may be included in the Appendix; however, a copy of any such photograph must also be included within the Research Plan and within the page limitations (see Appendix for further instructions). **A twelve page absolute maximum will be strictly enforced. Applications that exceed this limit, or that exceed the type size limitations, will be returned without review.** You may use any page distribution within this overall limitation adhering to the following format:

**B. Specific Aims.** State the broad, long-term objectives and describe concisely and realistically what the specific research described in this application is intended to accomplish and any hypotheses to be tested.

**C. Background and Significance.** Briefly sketch the background to the present proposal, critically evaluate existing knowledge, and specifically identify the gaps in which the project is intended to fill. State concisely the importance of the research described in this application by relating the specific aims to the broad, long-term objectives.

**D. Preliminary Studies.** Provide an account of the principal investigator's preliminary studies pertinent to the application and/or any other information that will help to establish the experience and competence of the investigator to pursue the proposed project.

The titles and complete references to appropriate publications and manuscripts **accepted** for publication may be listed and included in the appendix of the application (no more than five such items).

**E. Research Design and Methods.** Outline the research design and the procedures to be used to accomplish the specific aims of the project. Include the means by which the data will be collected, analyzed, and interpreted. Describe any new methodology and its advantage over existing methodologies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. Provide a tentative sequence or timetable for the investigation. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.

**Gender and Minority Inclusion:** Applications for grants that involve human subjects are required to include minorities and both genders in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study. Special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders, and conditions in which disproportionately affect them.

**No specific number of pages is recommended for each section of the application, but the total for Sections B-E may not exceed 12 pages, including all tables and figures.**

**Although no specific page limitation applies to the following sections (F-H) of the application, be succinct.**

**F. Consultants/Collaborators.** Attach an appropriate letter from each individual confirming his or her role in the project. Do not place these letters in the appendix. Include Biographical Sketch pages for each consultant and collaborator and place them with those of the other participants on the project.

**G. Contractual Arrangements.** Provide a detailed explanation of the programmatic, fiscal, and administrative arrangements made between the applicant organization and the collaborating organizations and individuals. Attach confirming letters countersigned by an authorized official of the collaborating institutions and principal investigator or copies of written agreements.

**H. Literature Cited.** Do not scatter literature citations throughout the text. List them at the end of the Research Plan. Each literature citation must include the title of the article, the names of all authors, the name of the book or journal, volume number, page numbers, and year of publication. Make every attempt to be judicious in compiling a relevant and current list of literature citations. **Do not exceed four (4) pages.**

### **SPECIFIC INSTRUCTIONS - SECTION 3.**

**CONTINUATION PAGE.** May be used for those areas needing additional explanation.

**APPENDIX. ALL APPENDIX MATERIAL IS TO BE COMBINED INTO ONE (1) PDF DOCUMENT (SEPARATE FROM THE APPLICATION AND LETTERS) AND ATTACHED TO THE EMAIL SUBMITTING THE APPLICATION.**

**TITLE THE PDF DOCUMENT USING THE FORMAT: PRINCIPAL INVESTIGATOR (LAST, FIRST, MIDDLE) APPENDIX.**

**Do not mail or email this material separately.** The appendix **may not exceed five (5) items**, which may include publications or other printed material documenting preliminary studies. The Appendix is not to be used to circumvent the 12-page limit in the Research Plan. No page numbering is necessary for the Appendix